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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,072	10/14/2005	Ralf-Holger Voss	BB-140	1890

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EXAMINER	
MAKAR, KIMBERLY A	
ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,072	VOSS ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23, 27-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19, drawn to methods of making a heterodimeric specific wild type or chimeric T-cell receptor (TCR).

Group II, claim(s) 20-21, drawn to a mutated alpha or beta chain protein of a TCR.

Group III, claim(s) 22-23, drawn to a composition comprising an isolated nucleic acid encoding of a mutated alpha or beta chain TCR.

Group IV, claim(s) 27-28, drawn to a method for treatment of a cancerous disease in a patient by administering a mutated alpha-or beta chains of a TCR, or a recombinant T-cell expressing the mutant alpha or beta chains of the TCR.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions lack novelty. Backstom et al (listed in applicant's IDS dated 01/03/2006) teaches a mutant T cell receptor. It is noted for the record that claims 20-21 are drawn to product-by-process claims. According to MPEP 2113 "PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS." The process of producing the mutant alpha or beta chains do not appear to confer any patentably distinct features.

3. The technical feature of group I, drawn to a process of producing a mutant alpha or beta chain of a TCR is distinct from the technical feature of group II, drawn to a mutated alpha or beta chain protein of a TCR. The TCR of group II can be made using alternate methodologies. Thus groups I and II are biologically, functionally and compositionally distinct and capable of supporting individual patents.

4. The technical feature of group I, drawn to a process of producing a mutant alpha or beta chain of a TCR is distinct from the technical feature of group III, drawn to a composition comprising an isolated nucleic acid encoding of a mutated alpha or beta chain TCR. The isolated nucleic acids of group III are not produced by the methodologies of group I, and therefore require alternate reagents and protocols. Thus groups I and III are biologically, functionally and compositionally distinct and capable of supporting individual patents.

5. The technical feature of group I, drawn to a process of producing a mutant alpha or beta chain of a TCR is distinct from the technical feature of group IV, drawn to a method for treatment of a cancerous disease in a patient by administering a mutated alpha-or beta chains of a TCR, and a recombinant T-cell expressing the mutant alpha or beta chains of the TCR. The two groups comprise two distinct methodologies. The methodologies for treating a patient with a cancerous condition will require alternate methodologies that to simply produce a mutant TCR. Thus groups I and IV are biologically, functionally and compositionally distinct and capable of supporting individual patents.

6. The technical feature of group II, drawn to a mutated alpha or beta chain protein of a TCR is distinct from the technical feature of group III, drawn to a composition comprising an isolated nucleic acid encoding of a mutated alpha or beta chain TCR. The isolated nucleic acids of group III are compositionally distinct from the peptides of group II, and therefore are structurally and functionally different. The isolated peptides of group I do not necessarily have to produce the peptides of group II, but can be used as probes in an immunoblot, or the template for the generation of a PCR reaction, or a siRNA probe. Thus groups II and III are biologically, functionally and compositionally distinct and capable of supporting individual patents.

7. The technical feature of group II, drawn to a mutated alpha or beta chain protein of a TCR is distinct from the technical feature of group IV, drawn to a method for treatment of a cancerous disease in a patient by administering a mutated alpha-or beta chains of a TCR, or a recombinant T-cell expressing the mutant alpha or beta chains of the TCR. The mutant alpha or beta chain protein of a TCR of group II can be used in alternate methodologies, such as in a transgenic animal or in vitro cells expressing the mutant receptors in studies for analyzing T-cell activation pathways. Thus groups II and IV are biologically, functionally and compositionally distinct and capable of supporting individual patents.

8. The technical feature of group III, drawn to a composition comprising an isolated nucleic acid encoding of a mutated alpha or beta chain TCR is distinct from the technical feature of group IV, drawn to a method for treatment of a cancerous disease in a patient by administering a mutated alpha-or beta chains of a TCR, or a recombinant T-cell expressing the mutant alpha or beta chains of the TCR. The mutant alpha or beta chain isolated nucleic acids of group III can be used in alternate methodologies, such as in the development of a transgenic animal or in vitro cells expressing the encoded mutant receptors in studies for analyzing T-cell activation pathways. Thus groups III and

IV are biologically, functionally and compositionally distinct and capable of supporting individual patents.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/12/28/07

/Joseph Woitach/
Joseph Woitach
SPE 1636